

**Notice of Allowability**

Application No.

10/071,490

Examiner

Blessing M. Fubara

Applicant(s)

MARCHOSKY, J. ALEXANDER

Art Unit

1618

**-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address--**

All claims being allowable, PROSECUTION ON THE MERITS IS (OR REMAINS) CLOSED in this application. If not included herewith (or previously mailed), a Notice of Allowance (PTOL-85) or other appropriate communication will be mailed in due course. **THIS NOTICE OF ALLOWABILITY IS NOT A GRANT OF PATENT RIGHTS.** This application is subject to withdrawal from issue at the initiative of the Office or upon petition by the applicant. See 37 CFR 1.313 and MPEP 1308.

1. ☒ This communication is responsive to response filed 3/7/06.
2. ☒ The allowed claim(s) is/are 97, 98, 103 and 104 (claims are renumbered).
3. ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some\* c) ☐ None of the:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

\* Certified copies not received: \_\_\_\_\_.

Applicant has THREE MONTHS FROM THE "MAILING DATE" of this communication to file a reply complying with the requirements noted below. Failure to timely comply will result in ABANDONMENT of this application.

**THIS THREE-MONTH PERIOD IS NOT EXTENDABLE.**

4. ☐ A SUBSTITUTE OATH OR DECLARATION must be submitted. Note the attached EXAMINER'S AMENDMENT or NOTICE OF INFORMAL PATENT APPLICATION (PTO-152) which gives reason(s) why the oath or declaration is deficient.
5. ☐ CORRECTED DRAWINGS (as "replacement sheets") must be submitted.
- (a) ☐ including changes required by the Notice of Draftsperson's Patent Drawing Review (PTO-948) attached
- 1) ☐ hereto or 2) ☐ to Paper No./Mail Date \_\_\_\_\_.
- (b) ☐ including changes required by the attached Examiner's Amendment / Comment or in the Office action of Paper No./Mail Date \_\_\_\_\_.
- Identifying indicia such as the application number (see 37 CFR 1.84(c)) should be written on the drawings in the front (not the back) of each sheet. Replacement sheet(s) should be labeled as such in the header according to 37 CFR 1.121(d).
6. ☐ DEPOSIT OF and/or INFORMATION about the deposit of BIOLOGICAL MATERIAL must be submitted. Note the attached Examiner's comment regarding REQUIREMENT FOR THE DEPOSIT OF BIOLOGICAL MATERIAL.

**DRAWINGS FILED 2/07/2003 are approved by the Examiner**

**Attachment(s)**

1. ☒ Notice of References Cited (PTO-892)
2. ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3. ☒ Information Disclosure Statements (PTO-1449 or PTO/SB/08),  
Paper No./Mail Date 6/13/03
4. ☐ Examiner's Comment Regarding Requirement for Deposit  
of Biological Material
5. ☐ Notice of Informal Patent Application (PTO-152)
6. ☒ Interview Summary (PTO-413),  
Paper No./Mail Date 5/12/06.
7. ☒ Examiner's Amendment/Comment
8. ☒ Examiner's Statement of Reasons for Allowance
9. ☐ Other \_\_\_\_\_.

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Examiner acknowledges receipt of amendment and remarks filed 03/07/06. Claims 97, 98, 103 and new claim 104 are pending.

#### **EXAMINER'S AMENDMENT**

1. An examiner's amendment to the record appears below. Should the changes and/or additions be unacceptable to applicant, an amendment may be filed as provided by 37 CFR 1.312. To ensure consideration of such an amendment, it MUST be submitted no later than the payment of the issue fee.

Authorization for this examiner's amendment was given in a telephone interview with Harley Blosser on 5/12/06.

The application has been amended as follows:

Claim 97. (currently amended) A composition as set forth in claim [95] 104 wherein the [bone material]cancellous bone, demineralized bone matrix and non-decalcified bone matrix consists essentially of bone allograft material.

Claim 103. (currently amended) The method of claim 98 wherein the [bone material]cancellous bone, demineralized bone matrix and non-decalcified bone matrix consists essentially of bone allograft material.

#### ***Allowable Subject Matter***

2. The following is an examiner's statement of reasons for allowance:

The primary reason for allowance is that the claimed composition is a combination of 3 bone types, namely cancellous bone, demineralized bone matrix and non-decalcified bone matrix in the amounts and proportions as claimed. The non-decalcified bone is ground cortical bone, which has not been demineralized and "is known to contain osteoinductive growth factors,"

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according to paragraph [0028] of the published application. The as filed specification clearly envisions excluding various parts of the composition as in the composition described in the last three lines of paragraph [0012] of the published specification and originally filed claim 56, thus supporting the consisting essentially of language of claim 104. Furthermore, a terminal disclaimer filed 5/20/2005 overcame the obviousness type rejection.

The closest prior art:

a). The composition of Sander et al. (EP 0 522 569, art of record) does not include non-decalcified bone matrix or ground cortical bone that has not been demineralized.

b). The graft material of Muschler (US 6,049,026 which is of record) while disclosing composite graft material containing, for example, isolated mineralized cancellous bone sections, powders or granules of mineralized bone, demineralized cancellous bone sections, powders or granules of demineralized bone, guanidine-HCl extracted demineralized bone matrix, sintered cortical or cancellous bone, coralline hydroxyapatite sold by INTERPORE under the trade name INTERPORE 500, or INTERPORE 200, and granular ceramics such as that incorporated into the bone graft substitute COLLAGRAFT sold by Zimmer, or filamentous sponges such as those made from collagen by Orquest, the composite bone graft material contains bone marrow aspirate (column 3, lines 23-32; column 4, lines 60-66; column 5, lines 1-2; Examples 2-9). The bone marrow aspirate is excluded from the composition as claimed.

c). Gertzman et al. (US 6,030,635) uses demineralized cortical and cortico-cancellous bone (column 4, lines 30-33, 35-37, 60-67) in the bone putty composition; one of the differences between Gertzman and the claimed invention is that the cortical bone tissue in Gertzman is demineralized while it is not in the claimed composition.

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Any comments considered necessary by applicant must be submitted no later than the payment of the issue fee and, to avoid processing delays, should preferably accompany the issue fee. Such submissions should be clearly labeled "Comments on Statement of Reasons for Allowance."

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Blessing M. Fubara whose telephone number is (571) 272-0594. The examiner can normally be reached on 7 a.m. to 5:30 p.m. (Monday to Thursday).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael G. Hartley can be reached on (571) 272-0616. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Blessing Fubara  
Patent Examiner  
Tech. Center 1600

A handwritten signature in black ink, appearing to read "B. Fubara", is written over the printed name of the examiner.